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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,116	08/06/2001	William F. McKay	4002-2803	9548

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EXAMINER

LE, EMILY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/923,116

Applicant(s)

MCKAY, WILLIAM F.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19, 42-49 and 51-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 42-49 and 51-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 20-41 and 50 are cancelled. Claims 1-19, 42-49 and 51-72 are now pending and currently under examination.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 43-47, 49, 51-59, 65 and 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163.06 states: When an amendment is filed in reply to an objection or rejection based on 35 U.S.C.112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

The claims recite "lyophilized collagen". This recitation is added to the claims in Applicant's 03/01/2005 submission. In Applicant's submission, Applicant did not specifically point out the support for any amendments made to the disclosure, which includes the claims. Nor can the Examiner find support for the newly added limitation,

"lyophilized collagen". Lyophization is defined by **Dorland's Illustrated Medical Dictionary**, Copyright 2002 W. B. Saunders, as the creation of a stable preparation of a biological substance (blood plasma, serum, etc.), by rapid freezing and dehydration of the frozen product under high vacuum. In the instant, no such process or action is noted for the collagen in Applicant's disclosure.

***Claim Rejections - 35 USC § 102/103***

4. Claims 42, 48 and 60-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al., U.S. Patent No. 4888366.
5. Claims 67-71 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chu et al., U.S. Patent No. 4888366.
6. Claims 1-8, 11-14, 18-19, 56-59 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366.
7. Claims 15-16, 54-55, 63-64 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Parsons et al., U.S. Patent No. 5106626.
8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Ducheyne et al., U.S. Patent No. 5874109.
9. Claims 9-10 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Urist, U.S. Patent No. 4795804.
10. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Michelson, U.S. Patent No. 5785710.

In response to the 102(b) and/or 103(a) rejections set forth in the previous office action, Applicant amends the claims to include the limitation(s): "three dimensionally stable but flexible"; and submits: Chu et al. does not teach the newly added limitation ""three dimensionally stable but flexible" for Chu et al. teaches of osteogenic sponge compositions that are "rigid with a compressive strength of at least 20 Newtons (N) per square centimeter".

Applicant's submission has been considered, however, it is not found persuasive for the following reason(s): Applicant has taken the teaching of Chu et al. outside of its intended context. In the instant, Chu et al. uses the term rigid, by the compressive modulus value, to evaluate the three-dimensional stability of the osteogenic composition. Chu et al. does not intend for the use of rigidity to imply an inherent lack of flexibility.

Furthermore, in the absence data for direct comparison, the final basis of compositional equality is based on the ingredients and the proportions of the ingredients used in the composition. Applicant suggests the use of 1% to 3% by weight of collagen. Chu et al. teaches the use of 2% to 3% by weight of collagen. Applicant suggests the use of 97% to 99% by weight of the particulate biocompatible mineral. Chu et al. teaches 97% to 98% by weight of the particulate biocompatible mineral. Ergo, based on a comparative teaching between the instant disclosure and the disclosure of Chu et al. it is determined that the osteogenic compositions are the same. Any characteristics describing the claimed osteogenic composition would be inherent features in the

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osteogenic composition of Chu et al. because the osteogenic compositions are indistinguishable.

11. Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by Smestad et al., U.S. Patent No. 5123925 in view of Chu et al.

In response to the original 102 (b) rejection set forth in the previous office action, Applicant amends the claims to include the limitation include the limitation(s): "three dimensionally stable but flexible"; and submits that Smestad et al. does not teach a high mineral to collagen ration and a three dimensionally stable but flexible" composition.

Applicant's submission has been considered, however, it is not found persuasive. Contrary to Applicant's assertion, the composition of Smestad et al. has a high mineral to collagen ration. Applicant teaches the use of the 1% to 3% by weight of collagen and 97% to 99% by weight of the particulate biocompatible mineral. In the instant, Smestad et al. teaches the use of 2% to 3% collagen and 97% to 98% of the particulate biocompatible mineral, see claim 1 of Smestad et al. Additionally, the composition of Smestad et al. is three dimensionally stable and flexible, see the discussion provided in columns 7-8 of Smestad et al. Smestad et al. teaches a process that permits the optimization of the three dimensional stability and flexibility of the structure. Furthermore, in the absence of direct comparison of physical testing data, the final basis of compositional equality is based on the ingredients and the proportions of the ingredients used in the composition. Applicant suggests the use of 1% to 3% by weight of collagen. Smestad et al. teaches the use of 2% to 3% by weight of collagen. Applicant suggests the use of 97% to 99% by weight of the particulate biocompatible

mineral. Smestad et al. teaches 97% to 98% by weight of the particulate biocompatible mineral. In the instant, the composition of Smestad et al. and the claimed composition are the same. Any characteristics describing the claimed composition would be inherent features in the composition of Smestad et al. because the claimed composition and the composition of Smestad et al. are indistinguishable.

***Claim Rejections - 35 USC § 103***

12. Claims 43, 45-47 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366.

In response to the original 102 (b) rejection set forth in the previous office action, Applicant amends the claims to include the limitation "lyophilized collagen" and submits that Chu et al. fails to teach the use of lyophilized collagen.

The following rejection is only submitted into the record should Applicant finds adequate support for the limitation "lyophilized collagen", which has been rejected as new matter. Should Applicant cannot provide adequate support for the cited limitation, the rejection set forth in the previous office action, 102(b), is maintained.

While it is not readily apparent if Chu et al. uses a lyophilized form of collagen, however, it is noted that Chu et al. discloses the use of lyophilized collagen as acceptable substitutes for collagen in solution form. Chu et al. teaches that any non-reconstituted collagen preparation, e.g., lyophilized collagen, may be used. At the time the claimed invention was made, lyophilized collagen is known in the art, as clearly demonstrated by Chu et al. Ergo, should the collagen used by Chu et al. is not lyophilized collagen, as alleged by Applicant, it would have been prima facie obvious for

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one of ordinary skill in the art at the time the claimed invention was made to substitute the collagen preparation used by Chu et al. with other non-reconstituted collagen preparation, such as lyophilized collagen. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Chu et al. suggests the use of any non-reconstituted collagen preparations, including lyophilized collagen, as acceptable substitutes to the collagen preparation used by Chu et al.

13. Claims 43, 45-47 and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smestad et al., U.S. Patent No. 5123925 in view of Chu et al. U.S. Patent No. 4888366.

In response to the original 102 (b) rejection set forth in the previous office action, Applicant amends the claims to include the limitation "lyophilized collagen" and submits that Smestad et al. fails to teach the use of lyophilized collagen.

The following rejection is only submitted into the record should Applicant finds adequate support for the limitation "lyophilized collagen", which has been rejected as new matter. Should Applicant cannot provide adequate support for the cited limitation, the rejection set forth in the previous office action, 102(b), is maintained.

Smestad et al. does not teach the use of lyophilized collagen. Smestad et al. teaches the use of collagen in solution form, Zyderm ® collagen implant. However, lyophilized collagen is known in the art at the time the invention made, as evidenced by Chu et al. Chu et al. discloses the use of two forms of fibrillar collagen, lyophilized collagen, Collagenfleece®, and collagen in solution form, Zyederm ® collagen implant.



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Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the claimed invention was made to substitute one form of fibrillar collagen for another. One of ordinary skill in the art would have had a reasonable expectation of success for doing so because collagen in solution form and lyophilized collagen are art recognized forms of fibrillar collagen.

### ***Conclusion***

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

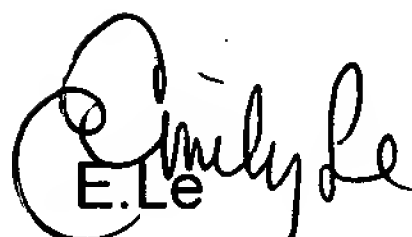
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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